

ENFORCEMENT CASE REVIEW	I. PRODUCT REGISTRATION STATUS
ECR Log No. FY11-X-0	
Product Label	
BRAND NAME: Liquid Fence® Rabbit Repellent, Liquid Fence® Deer & Rabbit Repellent, Liquid Fence® Deer & Rabbit Repellent Granular WEBSITE(S): www.liquidfence.com	COMPANY NAME: The Liquid Fence® Company, Inc. COMPANY ADDRESS: P.O. Box 300 Brodheadsville, PA 18322

Basic Registration Status

<input type="checkbox"/> REGISTERED	
DATE REGISTERED:	EPA REGISTRATION NO.:
REGISTRANT NAME:	REGISTRANT ADDRESS:

<input checked="" type="checkbox"/> UNREGISTERED	
<input checked="" type="checkbox"/> NO REGISTRATION APPLICATION	
<input type="checkbox"/> APPLICATION PENDING	FILE SYMBOL:
<input type="checkbox"/> CANCELED/SUSPENDED	DATE: (m/d/yyyy)
<input type="checkbox"/> REGISTRANT REQUESTED <input type="checkbox"/> NONPAYMENT OF MAINTENANCE FEES <input type="checkbox"/> CANCELLATION / SUSPENSION ORDER OF: <input type="checkbox"/> OTHER:	↓ DEADLINES (m/d/yyyy) FOR: EXISTING STOCKS: DISTRIBUTOR: USER DEADLINE:
<input type="checkbox"/> EXEMPTED: (UNDER 40CFR SECTION:)	

Distributor Registration Status

SUPPLEMENTAL REGISTRATION <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	DATE: SUPPLEMENTARY REGISTRATION: (m/d/yyyy)
DISTRIBUTOR NAME:	DISTRIBUTOR ADDRESS:
PRODUCT NAME:	

Pertinent Registration Information

Product is sold and distributed as exempt under 40 C.F.R. § 152.25(f).
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Pesticide / Device Status

IS THIS A PESTICIDE? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO (40CFR152.15)	<input type="checkbox"/> NO PESTICIDAL CLAIMS	<input type="checkbox"/> NO PESTICIDAL EFFECT
IS THIS A DEVICE? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO (40CFR152.500)		

Pest Control Claims and Other Factors That Identify the Product as a Pesticide or Device (including labeling and advertising)

The labels for three repellent products, produced and sold by The Liquid Fence Company, Inc., attached to this enforcement case review (ECR) are pesticide products intended to repel deer and/or rabbits. These products have never been federally registered, and no registration application has been received from The Liquid Fence Company, Inc. by EPA.

ENFORCEMENT CASE REVIEW		II. CONCERNS	
ECR Log No. FY11-X-0			
		Product Labeling	
BRAND NAME: Liquid Fence® Rabbit Repellent, Liquid Fence® Deer & Rabbit Repellent, Liquid Fence® Deer & Rabbit Repellent Granular		COMPANY NAME: The Liquid Fence® Company, Inc.	
WEBSITE(S): www.liquidfence.com		COMPANY ADDRESS: P.O. Box 300 Brodheadsville, PA 18322	

Review

The Oregon Department of Agriculture (ODA) referred a case involving several Liquid Fence Company, Inc. products to EPA's Region 10 that had been submitted by that company for state registration. The ODA denied the registrations based on the grounds the products were labeled for use on food crops, but contained putrescent eggs and sodium lauryl sulfate, neither of which had met criteria for exemption from the requirement of a tolerance as pesticide active ingredients. ODA subsequently received a complaint from a competitor of Liquid Fence Company, Inc. concerning the food uses on products containing putrescent eggs and sodium lauryl sulfate as active ingredients.

Region 10 asked the Biopesticides and Pollution Prevention Division (BPPD) to determine if one of the products, "Liquid Fence® Deer and Rabbit Repellent," meets the Minimum Risk Pesticides exemption outlined in 40 CFR 152.25(f), and in particular whether:

- 1) The active ingredient, Sodium Lauryl Sulfate (SLS), classifies as an edible oil or fat under 40 CFR 180.950(c), and therefore is exempt from the requirement of a tolerance; and if
- 2) The labeling for Deer and Rabbit Repellent adequately restricts the use of this product on edible crops as outlined in 40 CFR 180.1071(a)(11) for products containing eggs.

Additionally, Region 10 requested BPPD to provide examples of label language that would adequately meet the restriction in 40 CFR 180.1071(a)(11) if it was determined that the current language was not adequate.

FIFRA § 25(b) states that "[t]he Administrator may exempt from the requirements of this Act by regulation any pesticide which the Administrator determines ... to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act." The criteria for exemption of "Minimum risk pesticides" are described at 40 CFR 152.25(f). In order to be exempt as a minimum risk pesticide, a product must meet all of the following criteria:

- (1) Must contain active ingredients listed under 40 CFR 152.25(f)(1)
- (2) Must contain inert ingredients in the most current List 4A (40 CFR 152.25 (f)(2))
- (3) Must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient (40 CFR 152.25(f)(3)(i))
- (4) Must not bear claims to control or mitigate microorganisms that pose a threat

- to human health or claims to control insects or rodents carrying specific diseases
(40 CFR 152.25(f)(3)(ii))
- (5) Must not include false and misleading statements (40 CFR 152.25(f)(3)(iii))

Information concerning minimum risk pesticides is easily accessed at EPA's website:
http://www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm.

To answer the general question of whether "Liquid Fence® Deer and Rabbit Repellent," submitted with the ECR request, meets the Minimum Risk Pesticides exemption outlined in 40 CFR 152.25(f), the Biopesticides and Pollution Prevention Division (BPPD) reviewed the product's label to determine if each of the active ingredients listed on the label include each ingredient's percent by weight in the product. The numbers are somewhat blurred on the submitted label, but appear to be:

- 1) Putrescent Egg Solids 1.54%
- 2) Garlic 0.18%
- 3) Sodium Lauryl Sulfate 0.04%
- 4) Potassium Sorbate 0.03%

BPPD also noted that the label lists "Other Ingredients" as: Water, Xantham Gum.

The exemption of minimum risk pesticides under Section 25(b) of FIFRA, described at 40 CFR 152.25(f), is an exemption (from federal registration) under FIFRA only. As a result, a tolerance or a tolerance exemption under Section 408 of FFDCA must be established for the ingredients of a pesticide if the use of the pesticide results in residues in or on food commodities.

BPPD found that garlic and potassium sorbate (sorbic acid, potassium salt) are exempt from the requirement of a tolerance as either active or inert ingredients in pesticide formulations (40 CFR 180.950(a) and (e), respectively). Water and xantham gum are also exempt from the requirement of a tolerance (40 CFR 180.950(a) and (e), respectively).

In accordance with criterion (1) for "Minimum risk pesticides," all four of the active ingredients in "Liquid Fence® Deer and Rabbit Repellent" are included on the list of active ingredients at 40 CFR 152.25(f)(1). Water and xantham gum are permitted as inert ingredients, so criterion (2) is met. Criterion (3) is met, since the name and percentage by weight is included for each of the active ingredients. Criterion (4) is met, since there are no claims to control or mitigate microorganisms that pose a threat to humans, nor claims to control insects or rodents carrying specific diseases. Criterion (5) is not met, due to food use claims that are false and misleading, for reasons that are discussed, below.

Response to Question 1:

Sodium lauryl sulfate is only exempt from FIFRA as a minimum risk pesticide active ingredient, but a tolerance or tolerance exemption has not been established for its use as an active ingredient in a pesticide formulation. Further, it is not on the approved list of inerts that may be included in a minimum risk pesticide. This ingredient is only exempt from tolerance when it is an ingredient in registered pesticide formulations with the following limitations:

- 1) Pre- and Post-harvest uses as a surfactant – an inert use – in accordance with 40 CFR 180.910: Alkyl (C8-C18) sulfate and its ammonium, calcium, isopropylamine, magnesium, potassium, sodium, and zinc salts.
- 2) Application to animals as a surfactant – an inert use – in accordance with 40 CFR 180.930: Alkyl (C8-C18) sulfate and its ammonium, calcium, isopropylamine, magnesium, potassium, sodium, and zinc salts.
- 3) Use as an ingredient – active or inert is not specified – in an antimicrobial formulation applied to food processing equipment and utensils, in accordance with 40 CFR 180.940: Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate), CAS No. 151-21-3.

Sodium lauryl sulfate is not an edible fat or oil as described in 40 CFR 180.950(c). It is a well-known surfactant used as a cleaning agent and in various personal care commodities (cosmetics, shampoos, bubble bath, shaving cream). Sodium lauryl sulfate is made from lauric acid, a component of coconut oil. Lauric acid is converted into a fatty alcohol, then sulfonated to make lauryl sulfate. Lauryl sulfate is reacted with sodium hydroxide to produce sodium lauryl sulfate.

In accordance with 21 CFR 172.822, sodium lauryl sulfate is a food additive permitted (under FFDCA) for direct addition to food for human consumption, for use or intended use as:

- 1) An emulsifier in or with egg whites whereby the additive does not exceed the following limits: egg white solids, 1,000 ppm; frozen egg whites, 125 ppm; liquid egg whites, 125 ppm;
- 2) A whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows;
- 3) A surfactant in:
 - (i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the Act precludes such use.
 - (ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the Act precludes such use.
- 4) As a wetting agent at a level not to exceed 10 parts per million in the partition of high and low melting fractions of crude vegetable oils and animal fats, provided that the partition step is followed by a conventional refining process that includes alkali neutralization and deodorization of the fats and oils.

(42 FR 14491, Mar. 15, 1977, as amended at 43 FR 18668, May 2, 1978)

Sodium lauryl sulfate is not included in 21 CFR part 172, subpart D: Special Dietary and Nutritional Additives. A search of the internet concerning whether sodium lauryl sulfate is considered an edible fat or oil, and/or had nutritional value, returned no information. There were many “hits” concerning its use as a detergent, a surfactant, and in pharmaceuticals and personal care products. It is important to note, however, that 21 CFR part 172, subpart D does not apply to residues of any of the listed food additives

that result in food and animal feed commodities as a result of pesticidal use.

Minimum risk pesticide manufacturers must never use an inert ingredient from List 4A as an active ingredient unless the ingredient is included on the list of active ingredients found at 40 CFR 152.25(f); the reverse applies to the exempt active ingredients being used as inerts in these products.

Response to Question 2:

Putrescent Egg Solids are exempt from the requirement of a tolerance in or on food commodities, but because eggs are one of the top eight food allergens, its food uses are limited, as defined in the tolerance exemption (40 CFR 180.1071(a)(1) through (14)):

- 1) Use in pesticide products intended to treat seeds.
- 2) Use in nursery and greenhouse operations, as defined in 40 CFR 170.3, which include seeding, potting and transplanting activities.
- 3) Pre-plant and at-transplant applications.
- 4) Incorporation into seedling and planting beds.
- 5) Applications to cuttings and bare roots.
- 6) Applications to the field that occur after the harvested crop has been removed.
- 7) Soil-directed applications around and adjacent to all plants.
- 8) Applications to rangelands, which is land, mostly grasslands, whose plants can provide food (i.e., forage) for grazing or browsing animals.
- 9) Use in chemigation and irrigation systems (via flood, drip, or furrow application with no overhead spray applications).
- 10) Application as part of a dry fertilizer on which an active ingredient is impregnated.
- 11) Aerial and ground applications that occur when no above-ground harvestable food commodities are present (usually pre-bloom).
- 12) Application as part of an animal feed-through product.
- 13) Applications as gel and solid (non-liquid/non-spray) crack and crevice treatments that place the gel or bait directly into or on top of the cracks and crevices via a mechanism such as a syringe.
- 14) Applications to the same crop from which the food commodity is derived, whether the plant fraction(s) intended for harvest are present or not, e.g., applications of peanut meal when applied to peanut plants.

The label for "Liquid Fence® Deer and Rabbit Repellent" does not adequately restrict the use of this product on edible crops (40 CFR 180.1071(a)(11)) for products containing eggs. The label bears an illustration of a green leaf with "For use on edible crops!" in yellow boldfaced font across the surface of the leaf on the front panel and in the directions for use. The directions state, "Apply liberally to plants and their perimeter during a dry period. Repeat process 1 week later and then approximately once per month thereafter. Areas where feeding pressure from deer and rabbits is intense, spray Liquid Fence® Deer and Rabbit Repellent once a week for three weeks, then approximately once a month thereafter. ... Do not apply to above ground edible crops before harvest." This statement would need to be revised in order to meet the requirements for exemption from the requirement of a tolerance (refer to 40 CFR 180.1071(a)(11)).

Response to Question 3

If the only issue concerning "Liquid Fence® Deer and Rabbit Repellent" was the appropriateness of the label statements and directions for use, in light of the tolerance exemption for putrescent egg solids, then as indicated in item 11 in the Response to Question 2 section, above, the label statement, "Do not apply to above ground edible crops before harvest" would need to be modified, since "before harvest" includes the time period when edible food commodities are present. An appropriate example of the label's directions for use would be, "Do not apply to plants when harvestable food commodities are present, including blossoms." The directions to re-apply the product frequently over the growing season must be clarified so the user knows not to apply it once the food commodity appears on the plant. The green leaf logo with the "For use on edible crops" claim is misleading in not addressing the limitations regarding direct application of the product (containing eggs) to plants/crops once food commodities are present.

Since the concerns raised regarding "Liquid Fence® Deer and Rabbit Repellent" also include sodium lauryl sulfate as an active ingredient, and this active ingredient does not have an established tolerance or exemption from tolerance as an active ingredient (and only limited uses as an inert ingredient), the product cannot be used in or on food commodities as formulated, until a tolerance or tolerance exemption is established for sodium lauryl sulfate as a pesticide active ingredient in or on the intended food or feed commodities.

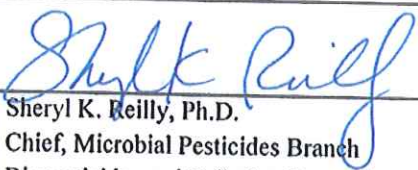

Other Labels Submitted with this ECR:

Though not requested, BPPD reviewed the other two labels attached to the ECR, and found that "Liquid Fence® Rabbit Repellent," which also contains sodium lauryl sulfate and putrescent egg solids, bears the same leaf illustration and claim, "For use on edible crops!" and the same (inadequate) restriction, "Do not apply to above ground edible crops before harvest," as "Liquid Fence® Deer and Rabbit Repellent." "Liquid Fence® Deer and Rabbit Repellent Granular" also contains sodium lauryl sulfate and putrescent egg solids. The product bears the same leaf and claim, "For use on edible crops!" and the directions for use include direct application to plants, including "vegetable gardens," but there are no restrictions concerning pre-harvest applications to edible crops.

Conclusion:

"Liquid Fence® Deer and Rabbit Repellent" does not meet criteria for exemption from registration under FIFRA § 25(b) as a minimum risk pesticide (40 CFR § 152.25(f)), due to its claimed food uses for

sodium lauryl sulfate and putrescent egg solids. Sodium lauryl sulfate is on the list of minimum risk pesticides (40 CFR 152.25(f)) as an active ingredient, but is not on the list of approved inert ingredients for use in minimum risk pesticides. As an active ingredient, it is not exempt from the requirement of a tolerance. Putrescent egg solids are also included on the list of minimum risk pesticides, and there is a tolerance exemption for residues of this food allergen (and others), but the uses are restricted. The directions for use on this product must be revised to meet the requirements for putrescent egg solids to meet the exemption from the requirement of a tolerance for preharvest aerial and ground applications to edible food commodities in accordance with 40 CFR 180.1071(a)(11).

REVIEWER NAME/SIGNATURE	APPROVING AUTHORITY NAME/SIGNATURE	DATE
 Sheryl K. Reilly, Ph.D. Chief, Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs	 Keith A. Matthews, Director Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs	1/3/12